TELE-INDUCTION OF BUPRENORPHINE FOR OPIOID USE DISORDER: REGULATORY FLUX AND PUBLIC CONFUSION

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INTRODUCTION

Consider an individual named Taylor who has opioid use disorder (OUD), defined by the American Psychiatric Association as a "problematic pattern of opioid use leading to clinically significant impairment or distress."[1] Taylor would like to try buprenorphine,[2] a medication approved by the Food

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1. *See* AM. PSYCH. ASS'N, DIAGNOSTIC & STATISTICAL MANUAL OF MENTAL DISORDERS (5th ed., text rev. 2022) (describing the manifest conditions to include, but not to be limited to: "[o]pioids are often taken in larger amounts or over a longer period than was intended"; "[t]here is a persistent desire or unsuccessful efforts to cut down or control opioid use"; and "[r]ecurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home").

2. *See* SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., BUPRENORPHINE: QUICK START GUIDE (2023) (explaining that buprenorphine can diminish the effects of physical dependency to opioids, such as withdrawal symptoms and cravings, and that buprenorphine prevents withdrawal in patients with OUD).

and Drug Administration (FDA) for maintenance and withdrawal management treatment ("treatment") of OUD.[3] Assume Taylor lives in a rural community located a considerable distance from the closest practitioner who provides in-person treatment to individuals with OUD.[4] Further assume that Taylor does not own a car and that public transportation is nonexistent in their rural area.[5] However, Taylor does have a smart phone with audio and video capabilities.[6] This Essay summarizes illustrative legal developments that address whether individuals like Taylor who have not received a prior, in-person, medical evaluation may receive an initial (or first) prescription of buprenorphine through audio-video or audio-only telemedicine.[7] More succinctly, this Essay examines illustrative developments in federal and state law that permit individuals like Taylor to receive a telemedicine induction ("tele-induction") of buprenorphine.[8]

This Essay proceeds as follows. Part I reviews federal developments relating to the tele-induction of buprenorphine for the treatment of OUD.

3. *See generally* DRUG ENF'T ADMIN., DIVERSION CONTROL DIV., DRUG & CHEMICAL EVALUATION SECTION, BUPRENORPHINE (2022), https://www.deadiversion.usdoj.gov/drug_chem_info/buprenorphine.pdf [https://perma.cc/2RXM-R33Z]; Christian Heidbreder, Paul J. Fudala & Mark K. Greenwald, *History of the Discovery, Development, and FDA-Approval of Buprenorphine Medications for the Treatment of Opioid Use Disorder*, DRUG & ALCOHOL DEPENDENCE REP., Mar. 2023 (providing historical information regarding the FDA's approval of buprenorphine for the treatment of OUD). This Essay, which focuses on the telemedicine induction ("tele-induction") of buprenorphine for maintenance and withdrawal management of individuals with OUD, does not address any other controlled substances approved by the FDA for the treatment of OUD, such as methadone. This Essay does not focus on medications not classified as controlled substances, such as naltrexone. It focuses exclusively on the use of buprenorphine for the treatment of OUD, not the use of opioids more generally for pain.

4. *See generally* Erin G. Major, Courtenay Gilmore Wilson, Delesha M. Carpenter, J. Chase Harless, Grace Trull Marley & Bayla Ostrach, *Factors in Rural Community Buprenorphine Dispensing*, EXPL. RSCH. CLINICAL & SOC. PHARMACY, Mar. 2023 (explaining that many individuals with OUD who live in small and remote rural counties lack access to in-person OUD treatment providers).

5. *See* Frank Breve, Lisa Batastini, Jo Ann K. LeQuang & Gina Marchando, *Mobile Narcotic Treatment Programs: On the Road Again?*, CUREUS, Mar. 2022, at 2 (reporting that "[t]he barriers to OUD treatment are numerous and likely global: living too far from a clinic, lack of reliable transportation, lack of healthcare coverage, lack of funds, work or home schedules in conflict with clinic schedules, [and] chaotic living situations").

6. *See* Jordon D. Bosse, Kim Hofman, Katharina Wiest, P. Todd Korthuis, Ritwika Petluri, Kellie Pert & Stephen A. Martin, *Patient Evaluation of a Smartphone Application for Telehealth Care of Opioid Use Disorder*, ADDICTION SCI. & CLINICAL PRAC., Sept. 2022, at 9 (evaluating the usability of mobile phone applications that facilitate the delivery of OUD treatment via telehealth; concluding that "an appealing, easy-to-use app[lication] . . . could circumvent existing barriers and foster sustained recovery").

7. *See, e.g.*, COMM. OF EVALUATING CLINICAL APPLICATIONS OF TELEMEDICINE, INST. OF MED., TELEMEDICINE: A GUIDE TO ASSESSING TELECOMMUNICATIONS FOR HEALTH CARE 1 (Marilyn J. Field ed., 1996) (defining telemedicine as "the use of electronic information and communications technologies to provide and support health care when distance separates the participants.").

8. *See generally* Miriam Harris, Samantha Johnson, Sarah Mackin, Richard Saitz, Alexander Y. Walley & Jessica L. Taylor, *Low Barrier Tele-Buprenorphine in the Time of COVID-19: A Case Report*, J. ADDICTION MED., May 2020 (describing the use of videoconferencing for buprenorphine induction to help treat individuals with OUD).

Part I shows that federal regulations in this area were a moving target during the COVID-19 public health emergency (PHE) and still are following the PHE's expiration on May 11, 2023.[9] Under a Drug Enforcement Administration (DEA)-issued temporary federal rule that expires on December 31, 2024, buprenorphine may be tele-inducted for the treatment of OUD without a prior, in-person medical evaluation.[10] Whether federal flexibilities will survive beyond December 31, 2024, remains to be seen.[11]

Part II summarizes five illustrative state developments relating to the tele-induction of buprenorphine for the treatment of OUD. Part II shows that state regulation of the tele-induction of buprenorphine for the treatment of OUD also has been in constant flux, not only during the COVID-19 PHE but also since the DEA, on October 10, 2023, issued its temporary rule extending COVID-19 PHE telemedicine flexibilities through December 31, 2024.[12] This state flux has continued throughout 2023 and 2024, when the author was researching and writing this Essay. In some states, agencies have reversed their position on the permissibility of the tele-induction of controlled substances in general or buprenorphine in particular three times in the last two years and have given prescribers less than one month to comply with some of these changes.[13] Due to this regulatory instability, prescribers lack clarity regarding the permissibility of the tele-induction of buprenorphine for the treatment of OUD.[14] This lack of clarity is particularly concerning

9. *See infra* notes 29–61 and accompanying text (explaining the termination of the COVID-19 PHE and summarizing developments in federal law since then).

10. Temporary Rule: Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 Fed. Reg. 69879, 69880 (Oct. 10, 2023).

11. *See infra* note 60 and accompanying text (noting that the federal government is working to promulgate permanent federal regulations addressing the permissibility of the tele-induction of buprenorphine "by the fall of 2024").

12. Temporary Rule: Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 Fed. Reg. at 69880.

13. *See, e.g.*, Press Release, Ga. Composite Med. Bd., Update on COVID State of Emergency (Dec. 7, 2023), https://medicalboard.georgia.gov/press-releases/2022-04-16/update-covid-state-emergency [https://perma.cc/A5V2-ZBME] (last visited Sept. 21, 2024) (noting that on April 15, 2022, the Georgia Composite Medical Board ("Georgia Board") stated that it would "continue to recognize the federal authorization for the tele-prescribing of controlled substances without an in-person exam as long as it is allowed by the [U.S. Department of Health and Human Services (HHS)] and DEA and practitioners meet the criteria set forth in the DEA policy"); *infra* Part II(A)(1) (detailing two subsequent changes to this position dating December 2023 and January 2024 as well as a fourth statement in April 2024 confirming the third change); *see also* Ariel Hart, *Confusion as Georgia Medical Board Brings Back Limits on Virtual Prescriptions*, ATLANTA J. CONST. (Jan. 3, 2024), https://www.ajc.com/news/health-news/confusion-as-georgia-medical-board-hits-brakes-on-virtual-prescribing/RR7GLF5XNFHQNMZGLWXXUMSCXU/ [https://perma.cc/9C6M-FBUJ] (noting the outcry from prescribers who had only one month to comply with the second change).

14. *See, e.g.*, Ariel Hart, *Georgia Medical Board Restores Telehealth Prescribing Flexibility*, ATLANTA J. CONST. (Jan. 4, 2024), https://www.ajc.com/news/health-news/georgia-medical-board-restores-telehealth-prescription-rules-after-outcry/CKFR4Z5YL5GI5EQPXFTLJBUGBY/ [https://perma.cc/W9MU-KE32] (explaining that a December 2023 position change by the Georgia Board to reimpose prepandemic restrictions on virtual

considering that, in some states, it is a felony for a patient to attempt to obtain a prescription for a controlled substance from a provider without having the proper provider-patient relationship in place, as well as for a provider to prescribe a controlled substance prescription in the same situation.[15] Chaos in this area is particularly unfortunate given that regulatory stability is in everyone's best interest.[16]

I. FEDERAL DEVELOPMENTS

As of this writing, federal law allows individuals like Taylor to receive a tele-induction of buprenorphine for the treatment of OUD if certain requirements are met.[17] How federal law got to this point is of significant interest. On October 15, 2008, President George W. Bush signed into law the Ryan Haight Online Pharmacy Consumer Protection Act[18] (the "Ryan Haight Act" or "the Act"), which amended the Controlled Substances Act of 1971[19] (CSA).[20] The Ryan Haight Act generally required the dispensing of controlled substances by means of the internet to be predicated on a valid prescription involving at least one prior, in-person, medical evaluation of the patient.[21] That said, the Act also established seven permissible "practice of telemedicine" situations, pursuant to which practitioners were permitted to

prescribing led to "confusion and outcry from doctors" and noting that, in January 2024, the Georgia Board reversed its position yet again).

15. *See* KY. REV. STAT. § 218A.140(3)–(5) (West 2024). This is an illustrative Kentucky controlled substances law making it a felony for a person to "knowingly obtain or attempt to obtain a prescription for a controlled substance without having formed a valid practitioner-patient relationship with the practitioner" and for a different person to "assist a person in obtaining or attempting to obtain [such] a prescription." *Id.*

16. The author thanks Indiana University Bloomington Maurer School of Law Professor Jennifer Oliva for her help drawing this conclusion.

17. This Essay was completed on September 21, 2024, and the statements made in this Essay are current as of this date. As discussed *infra* note 60, the DEA and HHS are expected to release a final rule addressing the tele-induction of buprenorphine for the treatment of OUD in Fall 2024. The statements made in this Essay will need to be updated when this final rule is published.

18. Pub. L. No. 110-425, 122 Stat. 4820 (codified as amended in scattered sections of 21 and 28 U.S.C.).

19. Pub. L. No. 91-513, 84 Stat. 1242 (codified as amended in scattered titles of the U.S. Code).

20. Ryan Haight Online Pharmacy Consumer Protection Act of 2008, H.R. 6353, 110th Cong. (2008) (amending the CSA and codified as amended in scattered sections of 21 and 28 U.S.C.).

21. *See id.* § 2. This bill amended the CSA to add the following provision: "No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription." *Id.* The act further provides that "[t]he term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by . . . a practitioner who has conducted at least 1 in-person medical evaluation of the patient" and stating that "[t]he term 'in-person medical evaluation' means a medical evaluation that is conducted with the patient in the physical presence of the practitioner." *Id.* These requirements are codified at 21 U.S.C. § 829(e)(1)–(2).

prescribe controlled substances despite never having conducted prior, in-person, patient evaluations.[22] The fourth of the seven situations involves:

> [T]he practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using [certain] telecommunications system[s] . . . during a public health emergency [PHE] declared by the Secretary [of the HHS] under . . . the Public Health Service Act . . . [and] involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates.[23]

This situation is hereinafter referred to as "the Telemedicine During a PHE Exception."

On January 31, 2020, Alex Azar, the former Secretary of the U.S. Department Health and Human Services (HHS), declared a PHE relating to COVID-19 under the Public Health Service Act[24] (PHSA), clarifying that the PHE started four days earlier on January 27, 2020.[25] Less than two months later, on March 16, 2020, Secretary Azar, in concurrence with the acting DEA Administrator, announced that the Telemedicine During a PHE Exception "applie[d] to all schedule II-V controlled substances in all areas of the United States."[26] The announcement clarified:

> Accordingly, as of March 16, 2020, and continuing for as long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they had not conducted an in-person medical evaluation, provided [that:] [1] the prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;

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22. H.R. 6353 § 2 ("Nothing in this subsection shall apply to . . . the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine") (codified at 21 U.S.C. § 829(e)(3)(A)); *id.* § 3 (amending section 102 of the CSA to add a fifty-fourth defined term, the "practice of telemedicine") (codified at 21 U.S.C. § 802(54)(A)–(G)).

23. *Id.* § 3 (amending § 102 of the CSA to add a fifty-fourth defined term which contains seven "practice of telemedicine" scenarios—the fourth of which is codified at 21 U.S.C. § 802(54)(D)).

24. Ch. 373, 58 Stat. 682 (codified as amended at 42 U.S.C. §§ 201–300mm-64).

25. Alex M. Azar II, *Determination that a Public Health Emergency Exists*, ADMIN. FOR STRATEGIC PREPAREDNESS & RESPONSE (Jan. 31, 2020), https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx [https://perma.cc/JNR6-ZF28].

26. *See COVID-19 FAQ*, U.S. DEP'T OF JUST., DRUG ENF'T ADMIN., https://www.deadiversion.usdoj.gov/faq/coronavirus-faq.html#:~:text=Question%3A%20Can%20telemedicine%20now%20be,Answer%3A%20Yes. [https://perma.cc/8Z3Y-98ZR] (last visited Sept. 21, 2024); Letter from Thomas W. Prevoznik, Deputy Assistant Adm'r, Diversion Control Div., Drug Enf't Admin., U.S. Dep't of Just., to Registrant (Mar. 31, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf [https://perma.cc/4ZWU-5G4C] ("Today, DEA notes that practitioners have further flexibility during the nationwide public health emergency to prescribe buprenorphine to new and existing patients with OUD via telephone by otherwise authorized practitioners without requiring such practitioners to first conduct an examination of the patient in person or via telemedicine.").

> [2] the telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and [3] the practitioner is acting in accordance with other Federal and State laws.[27]

HHS renewed the COVID-19 PHE thirteen times after its original declaration on January 31, 2020.[28] On February 9, 2023, the date of the PHE's thirteenth renewal, HHS Secretary Xavier Becerra announced that the COVID-19 PHE would officially expire on May 11, 2023.[29]

Between March 16, 2020 and May 11, 2023, federal law (via the Telemedicine During a PHE Exception) permitted authorized practitioners to prescribe controlled substances, including buprenorphine, to patients with OUD, despite never having conducted prior, in-person, evaluations of those patients, so long as the prescription was in accordance with other applicable federal and state laws.[30] By definition, however, the telemedicine flexibilities allowed under this exception would terminate at the expiration of the COVID-19 PHE on May 11, 2023.[31] On March 1, 2023, in anticipation of the expiration of the COVID-19 PHE, the DEA, in concert with HHS, issued two notices of proposed rulemaking (NPRMs).[32] The proposals would allow for the tele-induction of controlled substances, including buprenorphine, even where a prescriber had not conducted a prior, in-person evaluation.[33] The first NPRM will be referred to as the "General Telemedicine Proposed Rule."[34] The second NPRM will be referred to as the "Buprenorphine Proposed Rule."[35]

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27. *COVID-19 FAQ*, *supra* note 26.

28. These renewals occurred on April 21, 2020; July 23, 2020; October 2, 2020; January 7, 2021; April 15, 2021; July 19, 2021; October 15, 2021; January 7, 2022; April 12, 2022; July 15, 2022; October 13, 2022; January 11, 2023; and February 9, 2023. *See Current Emergencies*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/about-cms/what-we-do/emergency-response/current-emergencies [https://perma.cc/XB22-PBLV] (last visited Sept. 21, 2024).

29. Press Release, U.S. Dep't Health & Hum. Servs., Letter to U.S. Governors from HHS Secretary Xavier Becerra on Renewing COVID-19 Public Health Emergency (PHE) (Feb. 9, 2023), https://www.hhs.gov/about/news/2023/02/09/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html [https://perma.cc/D6JN-ZKJX] ("Based on current trends regarding COVID-19, the U.S. Department of Health and Human Services is planning for this to be the final renewal and for the COVID-19 PHE to end on May 11, 2023.").

30. *See supra* notes 22–23 and accompanying text.

31. *See supra* notes 22–23 and accompanying text (explaining that the in-person medical evaluation requirement did not apply to the dispensing of a controlled substance by a practitioner engaged in the "practice of telemedicine" and that the "practice of medicine" included telemedicine during a PHE).

32. *See* Expansion of Induction of Buprenorphine via Telemedicine Encounter, 88 Fed. Reg. 12890 (proposed Mar. 1, 2023) (to be codified at 21 C.F.R. pts. 1300, 1304, 1306); Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. 12875 (proposed Mar. 1, 2023) (to be codified at 21 CFR pts. 1300, 1304, 1306).

33. *See* Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. at 12875.

34. *See id.*

35. *See* Expansion of Induction of Buprenorphine via Telemedicine Encounter, 88 Fed. Reg. at 12890.

The Buprenorphine Proposed Rule proposed to permit the use of audio-video or audio-only telemedicine for the induction of buprenorphine for treatment of OUD without a prior, in-person, medical evaluation, but only if certain requirements were met.[36] One requirement was that the prescriber must be "authorized by state law, or not otherwise prohibited by state law, to engage in the practice of telemedicine in both the state where the practitioner is located as well as the state where the patient is located."[37] A second requirement of the Buprenorphine Proposed Rule was that the practitioner must prescribe "no more than a 30-day supply across all such prescriptions," including buprenorphine, "until the required medical evaluation" has been completed.[38] A third requirement was the completion of said medical evaluation.[39] The Buprenorphine Proposed Rule offered three options for this medical evaluation.[40] Under the *first option*, the patient must be evaluated and treated by, while in the physical presence of, the prescribing practitioner.[41] If the patient is not evaluated and treated by the prescriber who is in the patient's physical presence during such evaluation and treatment, the *second option* is an evaluation in which: (a) "the patient is treated by, and in the physical presence of, a DEA-registered practitioner (other than the prescribing practitioner)"; (b) the DEA-registered practitioner is "in the physical presence of the patient [and] is acting in the usual course of professional practice"; (c) state law is complied with; and (d) "[t]he remote prescribing practitioner, the patient, and the DEA-registered practitioner [who is] on site with the patient participate in a real-time, audio-video conference . . . [and] communicate simultaneously."[42]

A *third option* is for the evaluation to be conducted by a DEA registered practitioner who has:

> (a) issued a written qualifying telemedicine referral . . . for the patient to the prescribing practitioner; (b) [c]ommunicated the results of the evaluation . . . [including] the diagnosis, prognosis, and treatment, of the

36. These requirements include, but are not limited to: (1) the practitioner has obtained a DEA dispensing registration in the state where the practitioner is located; (2) the practitioner is authorized by state law, or is not otherwise prohibited by state law, "to engage in the practice of telemedicine in both the state where the practitioner is located as well as the state where the patient is located"; (3) the practitioner possesses "a 21 C.F.R. § 1301.13(e)(1)(iv) registration in order to prescribe a schedule III, IV, or V narcotic drug approved by the FDA specifically for use in the maintenance or detoxification treatment"; (4) the practitioner is "technically capable of using audio and video equipment permitting two-way, real-time interactive communication with the patient at the time of the telemedicine encounter"; and (5) the practitioner reviews and considers relevant prescription drug monitoring program (PDMP) data for a period of at least one year prior to issuing the prescription (or, if less than one year of data is available, the practitioner reviews and considers data for the entire available period), assuming the PDMP is operational. Expansion of Induction of Buprenorphine via Telemedicine Encounter, 88 Fed. Reg. at 12897–98, 12904–06 (proposing to amend 21 C.F.R. §§ 1304.03–.04 and proposing to add 21 C.F.R. § 1306.34).

37. *Id.* at 12897 (proposing to add 21 C.F.R. § 1306.34(a)(2)).

38. *Id.* at 12898 (proposing to add 21 C.F.R. § 1306.34(b)(4)).

39. *Id.* (proposing to add 21 C.F.R. § 1306.34(b)(5)).

40. *Id.* at 12905–06 (proposing to add 21 C.F.R. § 1306.34(b)(5)(i)–(iii)).

41. *Id.* at 12905 (proposing to add 21 C.F.R. § 1306.34(b)(5)(i)).

42. *Id.* (proposing to add 21 C.F.R. § 1306.34(b)(5)(ii)(A)–(D)).

> patient prior to the prescribing practitioner issuing the prescription; and (c) [h]as issued the written referral based on the diagnosis, prognosis or treatment that occurred as a result of the medical evaluation.[43]

The General Telemedicine Proposed Rule defined the term "qualifying telemedicine referral" as:

> [A] referral to a practitioner that is predicated on a medical relationship that exists between a referring practitioner and a patient where the referring practitioner has conducted at least one medical evaluation in the physical presence of the patient, without regard to whether portions of the evaluation are conducted by other practitioners, and has made the referral for a legitimate medical purpose in the ordinary course of their professional practice.[44]

To summarize, the Buprenorphine Proposed Rule would allow a practitioner to prescribe a thirty-day supply of buprenorphine for the treatment of OUD without a prior in-person evaluation assuming that certain other requirements are met.[45] One such requirement is that "no more than a 30-day supply" of buprenorphine can be prescribed until a required medical evaluation has been completed either by the prescribing practitioner or another DEA-registered practitioner, including a DEA-registered practitioner who has issued a written qualifying telemedicine referral.[46] The Buprenorphine Proposed Rule would authorize these prescriptions under the seventh, rather than the fourth, "practice of telemedicine" scenario listed in the CSA.[47] That is, these prescriptions would be authorized not by the Telemedicine During a PHE Exception but, instead, as a "circumstance[] that the Attorney General and the Secretary [of HHS] have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety."[48]

Public comments on both the General Telemedicine Proposed Rule and the Buprenorphine Proposed Rule were due to the DEA on or before March 31, 2023.[49] The DEA received 38,369 timely public comments on the General Telemedicine Proposed Rule and the Buprenorphine Proposed Rule.[50] Due to the extraordinary number of comments received, the DEA

43. *Id.* at 12905–06 (proposing to add 21 C.F.R. § 1306.34(b)(5)(iii)(A)–(C)).

44. Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. 12875, 12888 (proposed Mar. 1, 2023) (to be codified at 21 CFR pt. 1300) (proposing to add 21 C.F.R. § 1300.04(i) which defines qualified telemedicine referral).

45. *See supra* note 36 (listing these other requirements).

46. Expansion of Induction of Buprenorphine via Telemedicine Encounter, 88 Fed. Reg. at 12905 (proposing to add 21 C.F.R. § 1306.34(b)(4), (5)).

47. *See id.* at 12891–92, 12896 (stating that the Buprenorphine Proposed Rule is authorized pursuant to the seventh, not the fourth, "practice of telemedicine" scenario that is codified at 21 U.S.C. § 802(54)(G)).

48. *See* 21 U.S.C. § 802(54)(G) (codifying the seventh "practice of telemedicine" scenario).

49. Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. at 12875; Expansion of Induction of Buprenorphine via Telemedicine Encounter, 88 Fed. Reg. at 12890.

50. *See* Meeting Notice, 88 Fed. Reg. 52210, 52212 (Aug. 7, 2023).

was unable to finalize the NPRMs before the official expiration of the COVID-19 PHE on May 11, 2023. On May 10, 2023, one day before the expiration of the COVID-19 PHE, the DEA and HHS's Substance Abuse and Mental Health Services Administration (SAMHSA) issued a temporary rule extending the COVID-19 PHE telemedicine flexibilities ("First Temporary Rule") through November 11, 2023.[51] For any practitioner-patient telemedicine relationship established on or before November 11, 2023, the First Temporary Rule also provided a one-year grace period that allowed DEA-registered practitioners to prescribe controlled substances under the telemedicine flexibilities that were in place during the COVID-19 PHE through November 11, 2024.[52] The allowances set forth in the First Temporary Rule were authorized under the seventh, not the fourth, "practice of telemedicine" scenario listed in the CSA.[53] That is, the allowances were not authorized by the Telemedicine During a PHE Exception but, instead, were authorized under "circumstances that the Attorney General and the Secretary [of HHS] have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety."[54]

On August 7, 2023, the DEA announced that it would host telemedicine listening sessions on September 12 and 13, 2023, to receive additional input regarding the permissibility of tele-prescribing in the context of controlled substances.[55] Because the DEA still needed to process and evaluate the comments it received in response to the March 2023 NPRMs as well as the perspectives it received during the September 2023 telemedicine listening sessions,[56] the DEA and SAMHSA issued a Second Temporary Rule on October 10, 2023.[57] The Second Temporary Rule further extended the COVID-19 PHE telemedicine flexibilities for new practitioner-patient relationships through December 31, 2024, whether or not a telemedicine relationship had been established on or before November 11, 2023.[58]

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51. *See* Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 Fed. Reg. 30037 (May 10, 2023) (to be codified at 42 C.F.R. pt. 12).

52. *See id.*

53. 21 U.S.C. § 802(54)(G) (codifying the seventh "practice of telemedicine" scenario as "the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using [certain] telecommunications system[s] . . . which practice . . . is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety."); Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 Fed. Reg. at 30038 & nn.8–9, 30041–42 (stating that the First Temporary Rule is authorized pursuant to the seventh, not the fourth, "practice of telemedicine" scenario that is codified at 21 U.S.C. § 802(54)(G)).

54. *See* 21 U.S.C. § 802(54)(G).

55. *See* Meeting Notice, 88 Fed. Reg. at 52211.

56. *See* Temporary Rule: Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 Fed. Reg. at 69880–81.

57. *See id.* at 69879–83.

58. *Id*. at 69880.

According to the DEA and SAMHSA, the purpose of this Second Temporary Rule was to "ensure a smooth transition for patients and practitioners that have come to rely on the availability of telemedicine for controlled medication prescriptions."[59] The DEA explained that it would work to promulgate permanent federal regulations (rather than additional temporary rules) "by the fall of 2024."[60] Like the First Temporary Rule, the allowances set forth in the Second Temporary Rule are authorized under the seventh, not the fourth, "practice of telemedicine" scenario listed in the CSA.[61]

II. STATE DEVELOPMENTS

The extended (and repeatedly re-extended) COVID-19 PHE telemedicine flexibilities described above provide federal authorization for the prescription of controlled substances via telemedicine encounters through December 31, 2024, so long as there is compliance with other applicable federal and *state laws*.[62] Little academic attention has been given, however, to the question whether current (i.e., post-COVID-19 PHE) state laws are: (1) following the Second Temporary Rule and allowing the tele-induction of buprenorphine for the treatment of OUD via telemedicine encounters through December 31, 2024; (2) prohibiting the tele-induction of buprenorphine altogether notwithstanding the Second Temporary Rule; or (3) taking some other course of action with respect to the tele-induction of buprenorphine for the treatment of OUD.

As discussed in more detail below, state laws and developments relating to the tele-induction of buprenorphine for the treatment of OUD vary widely and, in many cases, have been in constant flux, including throughout 2024. Some states have enacted legislation, promulgated regulations, issued press releases, or made other public announcements stating that they are mirroring the Second Temporary Rule. That is, they are allowing the tele-induction of buprenorphine for the treatment of OUD through December 31, 2024, when the Second Temporary Rule's flexibilities will end.[63]

Other states are expressly prohibiting the tele-induction of buprenorphine for the treatment of OUD, and are requiring a prior, in-person medical evaluation notwithstanding the Second Temporary Rule.[64] Still other states are taking other approaches to the tele-induction of buprenorphine for the treatment of OUD.[65] Although a review of the laws in all fifty states is

59. *Id.*

60. *Id.*

61. *See id.* at 69880 nn.7–8, 69881 (stating that the Second Temporary Rule is authorized pursuant to the seventh, not the fourth, "practice of telemedicine" scenario that is codified at 21 U.S.C. § 802(54)(G)).

62. *See* Ryan Haight Online Pharmacy Consumer Protection Act of 2008, H.R. 6353, 110th Cong. § 3 (2008) (emphasis added) (amending the CSA and codified as amended in scattered sections of 21 and 28 U.S.C.).

63. *See infra* Part II.A.

64. *See infra* Part II.B.

65. *See* Stacey A. Tovino, *Dialing In or Dialing Out?: The Relationship Between State Telemedicine Law and Access to Buprenorphine*, 12 TEX. A&M L. REV. (forthcoming 2025)

beyond the scope of this Essay,[66] the remainder of this Essay provides two examples of states that are mirroring the Second Temporary Rule, two examples of states that are countering the Second Temporary Rule, and one example of a state that is taking a hybrid approach.

A. States Mirroring the Second Temporary Rule

1. Georgia

At present, and through December 31, 2024, Georgia is allowing the tele-induction of buprenorphine for OUD without a prior, in-person, medical evaluation, consistent with the DEA's Second Temporary Rule.[67] However, Georgia's position on this issue has been in constant flux and has been extraordinarily difficult for the author to track. Indeed, the Georgia Composite Medical Board ("Georgia Board") has changed its position regarding the permissibility of the tele-induction of controlled substances without a prior, in-person, medical evaluation at least three times through four different press releases over the last two years.[68] In its first press release on the issue, the Georgia Board stated on April 15, 2022 (i.e., during the federal COVID-19 PHE) that:

> Under the U.S. Department of Health and Human Services' public health emergency, DEA-registered practitioners may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided certain conditions are met. The [Georgia Board] will continue to recognize the federal authorization for the tele-prescribing of controlled substances without an in-person exam as long as it is allowed by the HHS and DEA and practitioners meet the criteria set forth in the DEA policy.[69]

On December 7, 2023, the Georgia Board issued a second press release, rescinding its April 15, 2022, position.[70] In this second press release, the Georgia Board explained that it had

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(manuscript at 10–45) (on file with author) (providing a fifty state survey of current state approaches to the tele-induction of buprenorphine to the treatment of OUD).

66. *See id.* (discussing state approaches not discussed in this Essay).

67. *See* Press Release, Ga. Composite Med. Bd., Board Rescinds Decision to End Tele-Prescribing Flexibilities Allowed by the Drug Enforcement Administration (Apr. 5, 2024), https://medicalboard.georgia.gov/press-releases/2024-04-05/board-rescinds-decision-end-tele-prescribing-flexibilities-allowed-drug [https://perma.cc/8V79-SBZK] ("During the April 2024 meeting, the Georgia Composite Medical Board reconsidered its position on the tele-prescribing flexibilities currently permitted by the Drug Enforcement Administration (DEA) and the U.S. Department of Health and Human Services (HHS) . . . . The Board will permit Georgia practitioners to continue to follow the DEA/HHS tele-prescribing flexibilities through December 31, 2024.").

68. *See infra* notes 69–79 and accompanying text.

69. Press Release, Ga. Composite Med. Bd., *supra* note 13 (citing *COVID-19 FAQ*, *supra* note 26).

70. Press Release, Ga. Composite Med. Bd., Board Updates Position on Telehealth Prescribing (Dec. 7, 2023), https://medicalboard.georgia.gov/press-releases/2023-12-07/board-updates-position-telehealth-prescribing [https://perma.cc/J5CE-YFMG].

> voted during its December 2023 meeting that effective Jan. 1, 2024, the Board's previous position on the flexibility allowed through the [DEA's] telehealth prescribing policy during and after the COVID-19 pandemic will be rescinded. All licensees should refer to the Medical Practice Act and Board Rules for proper prescribing practices in Georgia.[71]

The Georgia Board provided no explanation for its change of tack and told licensees that they would need to be in compliance with the new position by January 1, 2024.[72] Local newspapers reported confusion and outcry from Georgia doctors when they learned that they had less than a month to discontinue their tele-induction of controlled substances.[73]

Only a month after it issued its second press release, the Georgia Board issued a third press release on January 10, 2024, changing course once again.[74] The third press release provided:

> The [Georgia Board]'s telemedicine rules have been in effect since 2014, but the Board eased its rules due to the pandemic. As of May 1, 2024, all licensees should refer to the *Medical Practice Act* and Board Rules for proper prescribing practices in Georgia. Board Rules 360-3-.02 and 360-3-.07 address the appropriateness of prescribing and telemedicine.
>
> *Please note that an in-person visit is not required under the Board's rules for every prescription. In general, the Board rules require a patient to be examined once in-person prior to an initial prescription being issued for controlled substances and/or dangerous drugs. Additionally, a telemedicine provider must make diligent efforts to ensure patients are examined once annually in-person by a Georgia licensed physician, physician assistant, or nurse practitioner*. Prescribers should refer to the rules below to ensure they are in compliance with prescribing and patient care via electronic or other such means.[75]

The italicized language was especially confusing for Georgia licensees. The first italicized sentence suggested that there would be some scenarios, post-May 1, 2024, in which a prior in-person medical evaluation would not be required. Yet those scenarios are not discussed further. That said, the second italicized sentence stated a general rule that a prior in-person medical evaluation is required. Finally, the third italicized sentence requires telemedicine providers to make "diligent efforts to ensure" that patients are examined in person once per year but does not otherwise clarify what those "diligent efforts" are or what will happen if such "diligent efforts" are made but a patient does not actually appear once per year for the in-person evaluation. According to a newspaper article published in *The Atlanta*

71. *Id.*
72. *Id.*
73. *See, e.g.*, Hart, *supra* note 13 (reporting confusion and outcry from Georgia doctors).
74. Press Release, Ga. Composite Med. Bd., Board Extends Tele-Prescribing Flexibility Until May 1 (Jan. 10, 2024), https://medicalboard.georgia.gov/press-releases/2024-01-10/board-extends-tele-prescribing-flexibility-until-may-1 [https://perma.cc/J9T7-7E9Z].
75. *Id.* (emphasis added).

Journal-Constitution, the Georgia Board was going to "clarify its rules and revisit the issue by May 1."[76]

On April 5, 2024, the Georgia Board issued a fourth press release.[77] This most recent press release stated that the Georgia Board had decided to continue permitting Georgia practitioners to follow the Second Temporary Rule through December 31, 2024.[78] According to the Georgia Board, "[w]hile the DEA is working through the [notice and comment rulemaking process], the [Georgia] Board will be reviewing its own rules."[79]

2. New York

New York is another example of a state that has announced its intent to mirror the DEA's Second Temporary Rule. Like Georgia, New York's position on this issue has been in flux and also has been difficult for the author to track. New York's position has changed at least three times in the last year and a half.[80] In addition, a relevant New York regulation has been proposed but not finalized.[81]

As background, the Acting Commissioner ("Commissioner") of the New York State Department of Health issued a "determination letter" on January 31, 2023 (i.e., during the COVID-19 PHE) described as having the "force and effect of law."[82] This determination letter stated that, "for the duration of the federally declared public health emergency due to COVID-19, it is necessary for New York State patients to maintain access to controlled substance medications, including through the use of telemedicine."[83] Acknowledging that differences between federal and state laws can create confusion among practitioners, the determination letter provided:

> To provide maximum clarity for prescribers, pharmacists, and patients, this Commissioner's determination permits controlled substance prescribing through telemedicine pursuant to the same processes as Federal law and [DEA] policy permit, limited to the duration of the federally-declared public health emergency due to COVID-19, and provided it occurs in compliance with all other applicable Federal and New York State laws. This includes permitting the evaluation by telephone of patients for

76. Hart, *supra* note 14.
77. Press Release, Ga. Composite Med. Bd., *supra* note 67.
78. *Id.*
79. *Id.*
80. *See infra* notes 82–88 and accompanying text.
81. *See* 46 N.Y. Reg. 6 (May 15, 2024).
82. Letter from James V. McDonald, Acting Comm'r, N.Y. State Dep't of Health, to Practitioners and Pharmacists 1 (Jan. 31, 2023), https://www.health.ny.gov/professionals/narcotic/docs/2023-01-31_telemedicine_initial_exam.pdf [https://perma.cc/DNG4-GF2D]; Press Release, N.Y. State Dep't of Health, New York State Department of Health Issues Commissioner Determination for the Use of Telemedicine to Ensure Continued Access to Life Saving Medication for New Yorkers Struggling with Mental Health and Opioid Use Disorder (Jan. 31, 2023), https://www.health.ny.gov/press/releases/2023/2023-01-31_telemedicine.htm [https://perma.cc/8GA5-56Y3] (explaining the Commissioner's letter of the same date).
83. Letter from James V. McDonald to Practitioners and Pharmacists, *supra* note 82, at 1.

> buprenorphine for maintenance or detoxification treatment of an opioid use disorder, though not for any other controlled substance prescribing.[84]

However, two days after the determination letter was issued, the Chief Medical Officer (CMO) of the New York State Office of Mental Health stated in an informational bulletin that when the COVID-19 PHE expired on May 11, 2023, "[p]atients who have never been seen in person must be seen in person by the prescribing practitioner at least once prior to the renewal or new prescription for a controlled substance after the PHE ends."[85]

In August 2023, New York appeared to change tack once again. In particular, the New York State Office of Addiction Services and Supports (OASAS) released telehealth standards applicable to OASAS-certified prevention and treatment programs clarifying that, at least with respect to OASAS-certified programs, New York was following the First Temporary Rule.[86] Two months later, in October 2023, the New York State Department of Health's Bureau of Narcotic Enforcement (BNE), stated on its web page that "[f]ollowing the end of the federally declared public health emergency due to COVID-19, it is necessary for New York State patients to maintain access to medically necessary controlled substance medications, including through the use of telemedicine."[87] Notwithstanding its reminder to the public that "[p]ursuant to 10 NYCRR 80.63(d)(1), no controlled substance prescription shall be issued prior to the examination of the patient by the practitioner, except in limited circumstances," the BNE advised New Yorkers to "keep in mind that this examination may be conducted through telemedicine, provided that practitioners are in compliance with the [DEA's Second Temporary Rule]."[88]

On May 15, 2024, the New York State Department of Health released a proposed rule that would codify the website statements described above.[89] In particular, the proposed rule would allow a controlled substance to be prescribed through telemedicine, so long as the prescription is "consistent with all applicable state laws and regulations and the laws, rules and regulations of the Drug Enforcement Administration, United States

84. *Id.*

85. N.Y. STATE OFF. OF MENTAL HEALTH, INFORMATIONAL BULLETIN FROM OMH CHIEF MEDICAL OFFICER: PRESCRIPTION OF CONTROLLED SUBSTANCES AFTER THE FEDERAL PUBLIC HEALTH EMERGENCY FOR COVID-19, at 2 (2023), https://omh.ny.gov/omhweb/guidance/prescriptions-after-cv19-federal-emergency.pdf [https://perma.cc/FPA7-GEJM]. However, the informational bulletin also stated that "[p]atients who have been seen in person prior to or during the PHE by the practitioner prescribing the controlled medication may continue to be prescribed such medications using telehealth." *Id.* at 1.

86. N.Y. STATE OFF. OF ADDICTION SERVS. & SUPPORTS, TELEHEALTH STANDARDS FOR OASIS DESIGNATED PROVIDERS 9–10 (2023), https://oasas.ny.gov/system/files/documents/2023/08/telehealth.standards.pdf [https://perma.cc/5GF8-XWMH].

87. Bureau of Narcotics Enf't, *Prescribing Controlled Substances Using Telemedicine upon Expiration of the Federal COVID-19 Public Health Emergency*, N.Y. STATE DEP'T OF HEALTH (Oct. 2023), https://www.health.ny.gov/professionals/narcotic/ [https://perma.cc/3QGC-ZVR2].

88. *Id.*

89. 46 N.Y. Reg. 6, 7 (May 15, 2024). Note that the rule has not been published as of September 21, 2024.

Department of Justice, or any successor agency."[90] The proposed rule clarifies that its telemedicine permissions include "any controlled substance as approved by the [FDA] and the New York State Department of Health for the treatment of opioid use disorder."[91]

B. States Opposing the Second Temporary Rule

1. Louisiana

Louisiana is a prime example of a state that has recently enacted legislation that appears to prohibit, or could be interpreted to prohibit, the tele-induction of buprenorphine for the treatment of OUD notwithstanding the Second Temporary Rule. A Louisiana statute that became effective on January 1, 2024,[92] allows physicians with an unrestricted license to practice medicine and who use telehealth for any patient who "is being treated *at* a healthcare facility that is required to be licensed pursuant to the laws of this state and which holds a current registration with the [DEA]" to prescribe a "controlled dangerous substance without necessity of conducting an appropriate in-person patient history or physical examination of the patient."[93] A regulation contains the same language.[94] If a patient "is being treated *at* a [state-licensed and DEA-registered] healthcare facility," presumably (due to the use of the word "at") the patient is currently being treated at the facility or has presented to the facility in the past and therefore has received an in-person medical evaluation from someone at the facility in the past.[95] A second provision in the same Louisiana law prohibits a healthcare provider from "prescribing any controlled dangerous substance prior to conducting an appropriate in-person patient history or physical examination" except as authorized by the "appropriate state agency or professional or occupational licensing board or commission."[96] The author has yet to find a current rule promulgated by the Louisiana State Board of Medical Examiners (LSBME) or any other relevant agency or licensing board providing an exception. As a result, it appears that Louisiana's new law, effective January 1, 2024, could require an in-person medical evaluation of the patient (at some point) *at* a state-licensed, DEA-registered health care facility.

The Louisiana Society of Addiction Medicine (LASAM) supports this interpretation. In a letter dated August 16, 2023, LASAM expressed concern that the new Louisiana law "could be interpreted to require an in-person patient visit before practitioners can prescribe medications that treat opioid use disorder (OUD)" and asked the LSBME to adopt a regulation mirroring

90. *Id.*
91. *Id.*
92. S.B. 66, 2023 Reg. Sess. (La. 2023).
93. *See* LA. STAT. ANN. § 37:1271.1(A)(2) (2024) (emphasis added).
94. *See* LA. ADMIN CODE. tit. 46, pt. XLV, § 7513(C)(3)(a) (2021).
95. *See* LA. STAT. ANN. § 37:1271.1(A)(2) (2024) (emphasis added).
96. *See id.* § 40:1223.4(B)(6).

the telehealth flexibilities set forth in the DEA's Second Temporary Rule.[97] To date, the LSBME does not appear to have issued such a regulation.

2. Alabama

Other state laws very clearly prohibit the tele-induction of buprenorphine for the treatment of OUD. Alabama is a prime example. In 2022 (i.e., during the COVID-19 PHE), the Alabama Legislature enacted a new law providing that, "[a] prescription for a controlled substance may only be issued as a result of telehealth medical services" if, among other requirements, "[t]he prescriber has had at least one in-person encounter with the patient within the preceding 12 months.[98] The law went into effect on July 11, 2022, when federal flexibilities applied, suggesting specific state intent to counter such flexibilities.[99]

Since the enactment of the Alabama law, telehealth providers who were treating Alabama patients have scrambled to find ways to continue treating such patients. For example, Bicycle Health, the largest telehealth provider of treatments for OUD, rushed to find "in-person care options or otherwise face abandoning the [tele-based] treatment plan[s] they had built [in Alabama] via Bicycle Health."[100] In an operation dubbed "Alabama Airdrop," Bicycle Health actually flew staff to Alabama in 2022 and 2023 to perform hundreds of in-person medical examinations to enable its existing Alabama patients to continue receiving their buprenorphine prescriptions while complying with the new Alabama law, which requires at least one in-person encounter every twelve months.[101] Notwithstanding its airdrops, Bicycle Health has publicly stated that, as a result of the Alabama legislation, it will not accept new patients from Alabama going forward.[102]

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97. *See* Letter from Smita Prasad, President, La. Soc'y of Addiction Med., to Terrie R. Thomas, President, La. State Bd. of Med. Exam'rs (Aug. 16, 2023), https://downloads.asam.org/sitefinity-production-blobs/docs/default-source/advocacy/state-letters-and-comments/lasam-telehealth-letter-to-lsbme.pdf?sfvrsn=16457113_1 [https://perma.cc/TX6B-H5NJ] ("[W]e are concerned that the language of the statute could be interpreted to require an in-person patient visit before practitioners can prescribe medications that treat opioid use disorder (OUD) . . . . Until DEA releases a succeeding regulation [following the Second Temporary Rule], LASAM requests that the Board work to ensure that its regulations governing the use of telemedicine to treat OUD comport with the current federal regulation that does not require an in-person visit prior to the prescription of medications to treat OUD while engaging in the practice of telemedicine.").

98. ALA. CODE § 34-24-704(b)(1)(b) (2022).

99. S.B. 272, 2022 Reg. Sess. § 3 (Ala. 2022) (becoming effective ninety days after it was signed into law on April 12, 2022).

100. Press Release, Bicycle Health, Bicycle Health Doctors Fly to Alabama for a Second Year to Ensure Opioid Treatment Continuity for Patients (July 25, 2023), https://www.globenewswire.com/en/news-release/2023/07/25/2710506/0/en/Bicycle-Health-Doctors-Fly-to-Alabama-for-a-Second-Year-to-Ensure-Opioid-Treatment-Continuity-for-Patients.html [https://perma.cc/J2CC-M53S].

101. *Id.*; Ala. S.B. 272, § 3.

102. *See* Anastassia Gliadkovskaya, *Bicycle Health Flies Staff into Alabama to Save Hundreds of Its Patients from Losing Access to Care Under New Law*, FIERCE HEALTHCARE (July 20, 2022, 12:10 PM), https://www.fiercehealthcare.com/providers/bicycle-health-flies-physicians-alabama-maintain-patient-care-under-new-law [https://perma.cc/2TQV-UB4D].

C. Example of a Hybrid Approach

While some states are mirroring the Second Temporary Rule and others are countering it, still other states appear to be taking a hybrid approach. Kentucky is a prime example. Kentucky appears to permit the *initial* tele-*induction* of buprenorphine for the treatment of OUD.[103] That said, Kentucky does not appear to allow the subsequent *patient monitoring* to be carried out via telemedicine and, instead, requires in-person patient monitoring at progressively longer intervals as the patient recovers.[104] An opinion authored by the Kentucky Board of Medical Licensure in 2021 (i.e., during the COVID-19 PHE) appears to confirm this finding.[105]

As background, it is unethical and unprofessional conduct under the Kentucky Medical Practice Act[106] to prescribe or dispense any medication "[i]n response to any communication transmitted or received by computer or other electronic means, when the licensee fails to take the following actions to establish and maintain a proper physician-patient relationship."[107] A proper physician-patient relationship requires: (1) "[v]erification that the person requesting medication is in fact who the patient claims to be," (2) "[e]stablishment of a documented diagnosis through the use of accepted medical practices," and (3) "[m]aintenance of a current medical record."[108] Kentucky clarifies that "an electronic, on-line, or telephonic evaluation *by questionnaire* is inadequate for the initial evaluation of the patient or for any follow-up evaluation."[109] That said, Kentucky does not appear to prohibit a tele-evaluation (e.g., a verbal, back-and-forth, conversation with the patient via telemedicine during which the patient is evaluated), so long as such evaluation is not based on *just* a questionnaire.[110]

A Kentucky controlled substances law provides that the phrase "[p]ractitioner-patient relationship" as used in that law (but not other Kentucky laws), and for purposes of criminal prosecution only, "means a medical relationship that exists between a patient and a practitioner or the practitioner's designee, after the practitioner or his or her designee has conducted at least one . . . good-faith prior examination."[111] For purposes of criminal prosecution only, the same controlled substances law defines the phrase "good faith prior examination" as an "in-person medical examination of the patient" but also states that the phrase "in-person" includes "telehealth examinations."[112]

The same controlled substances law makes it a felony for a person to "knowingly obtain or attempt to obtain a prescription for a controlled

103. *See infra* note 132 and accompanying text.
104. *See infra* notes 121–26 and accompanying text.
105. *See infra* notes 130–33 and accompanying text.
106. KY. REV. STAT. ANN. § 311.597–.603 (West 2022).
107. *Id.* § 311.597(1)(e).
108. *Id.* § 311.597(1)(e)(1)–(3).
109. *Id.* § 311.597(1)(e) (emphasis added).
110. *See id.*
111. *Id.* § 218A.010(41).
112. *Id.* § 218A.010(18).

substance without having formed a valid practitioner-patient relationship with the practitioner"[113] and for any person to "assist a person in obtaining or attempting to obtain [such] a prescription."[114] These clauses could apply to patients seeking buprenorphine prescriptions as well as prescribers who write buprenorphine prescriptions.

Separate administrative regulations implementing the Kentucky Medical Practice Act contain a laundry list of additional requirements for licensees who prescribe, dispense, or administer buprenorphine for the treatment of OUD.[115] For example, the licensee shall recommend to the patient (but apparently not require of the patient) an "in-office observed induction protocol" and shall "supervise the in-office observed induction protocol."[116] However, "[i]f an in-office observed induction does not occur, the licensee shall appropriately record the circumstances in the patient chart."[117] Combined, these last two sentences seem to mean that: (1) an in-person induction of buprenorphine shall be recommended, but not required; and (2) if a non-in-person induction of buprenorphine takes place, the reasons why shall be documented in the medical record.

After an initial induction of buprenorphine, licensees "shall implement a treatment plan that requires objective behavioral modification by the patient. The behavioral modification shall include the patient's participation in a behavioral modification program that may include counseling or a twelve (12) step facilitation."[118] Moreover, the licensee shall ensure that the patient is *seen*: "(i) [n]o later than ten . . . days after induction and then at intervals of no more than ten . . . days for the first month after induction; and (ii) [a]t intervals of no more than fourteen . . . days for the second month after induction."[119] Although the regulations do not clarify whether the word "seen" means seen in person or seen online, the Kentucky Board of Medical Licensure's 2021 opinion seems to suggest that the word means in person.[120]

Moreover, if the patient demonstrates "objective signs of positive treatment progress, the licensee shall ensure that the patient is *seen* at least once monthly thereafter."[121] If, after two years of treatment, the patient demonstrates "objective signs of positive treatment progress, including documented evidence that the patient has been compliant with the treatment

113. *Id.* § 218A.140(3), (5).

114. *Id.* § 218A.140(4)–(5).

115. *See* 201 KY. ADMIN. REGS. 9:270 (2021) (setting forth regulations governing the "prescribing, dispensing, or administering of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone").

116. *Id.* § 2(4)(c)(1).

117. *Id.* § 2(4)(c)(1)(b).

118. *Id.* § 2(4)(e)(1).

119. *Id.* § 2(4)(e)(3)(a) (emphasis added).

120. *See* KY. BD. OF MED. LICENSURE, BOARD OPINION RELATING TO ONLINE/VIRTUAL MEDICATION ASSISTED TREATMENT (MAT) (2021), https://kbml.ky.gov/board/Documents/Board%20Opinion%20Relating%20to%20Online%20Virtual%20Medication%20Assisted%20Treatment.pdf [https://perma.cc/T2Z8-T98Z]. For a discussion of the 2021 opinion, see *infra* notes 130–33.

121. 201 KY. ADMIN. REGS. 9:270, § 2(4)(e)(3)(b)(i) (2021) (emphasis added).

plan and all treatment directives . . . then the licensee may require that the patient be *seen* only by the licensee at least once every three . . . months."[122] That said, "[t]he licensee shall *see* the patient in shorter intervals if the patient demonstrates any noncompliance with the treatment plan."[123] Licensees are also required to ensure that patients are drug tested.[124] Patients "in early stages of treatment shall be tested at least once weekly and as the patient becomes more stable in treatment, the frequency of drug testing may be decreased, but shall be performed at least on a monthly basis."[125] The statute also provides that "[i]ndividual consideration may be given for less frequent testing if a patient is in sustained remission."[126] Again, the regulations do not clarify whether the words "see" or "seen" mean seen in person or seen online.

Prior to, or at least within two weeks of initiating treatment, licensees must: (1) "obtain and record a complete and appropriate evaluation of the patient" including the history of present illness, history of substance use, social and family history, past medical and psychiatric histories, a *physical* examination of the patient, screening for HIV and hepatitis serology, and laboratory tests, including a complete blood count (CBC), a drug screen, and a comprehensive metabolic panel (CMP); (2) "[o]btain the patient's consent and authorizations in order to obtain the patient's prior medical records"; (3) "review and incorporate the information from the records into the evaluation and treatment of the patient"; (4) obtain and review a Kentucky All Schedule Prescription Electronic Reporting (KASPER) (prescription drug monitoring program (PDMP)) "report for that patient for the 12 month period prior to the initial patient encounter"; (5) explain the alternatives, risks, and benefits of buprenorphine treatment to the patient; (6) obtain written informed consent for buprenorphine treatment consistent with professional standards; and (7) if the patient is pregnant or capable of becoming pregnant, "they must meet additional requirements listed in the regulations."[127] Licensees who fail to comply with any of these requirements when prescribing, dispensing, or administering buprenorphine are considered to have departed from—and to have failed to conform with—"acceptable and prevailing medical practice" in Kentucky and may be subject to discipline and sanctions.[128]

In 2021 (i.e., during the COVID-19 PHE), the Kentucky Board of Medical Licensure issued an opinion on the issue.[129] The opinion clarified that it was "not a statute or administrative regulation and . . . does not independently have the force of law."[130] However, a licensee may be found to be in

122. *Id.* § 2(4)(e)(3)(b)(ii) (emphasis added).
123. *Id.* § 2(4)(e)(3)(b)(iii) (emphasis added).
124. *Id.* § 2(4)(e)(5)(f).
125. *Id.*
126. *Id.*
127. *Id.* § 2(4) (emphasis added).
128. *Id.* § 5.
129. *See* KY. BD. OF MED. LICENSURE, *supra* note 120.
130. *Id.* at 1.

violation of state law if the licensee practices in contravention of the Kentucky Board opinion.[131] The opinion provides in bold font on the first page:

> Telemedicine, as a substitute for, or in lieu of, the provision of in-person medical care is not appropriate in all circumstances. With regard to MAT for OUD, telemedicine has a role but is not appropriate for satisfying the standards of all components of a treatment program, particularly in regard to monitoring components.[132]
>
> *However, the use of telemedicine technologies to carry out monitoring components of treatment, such as through self-directed pills counts or unsupervised off-site drug screening methodologies, are wholly unreliable, and thus are inappropriate and counter to the intent of MAT for OUD*.[133]

Interestingly, the Kentucky Attorney General ("Kentucky AG") did sign on to a 2022 National Association of Attorneys General (NAAG) letter urging the DEA and SAMHSA to permanently extend telehealth flexibilities relating to the prescription of buprenorphine after the expiration of the COVID-19 PHE.[134] Because the NAAG letter only addresses the tele-*induction* of buprenorphine for the treatment of OUD and does not address the tele-*monitoring* of patients who are already on buprenorphine, the Kentucky AG's signature on the letter is not necessarily inconsistent with Kentucky's own regulations and the Kentucky Board of Medical Licensure's opinion, discussed above, which seem to prohibit the tele-*monitoring* of patients who are already on buprenorphine.[135] That said, it is possible that the Kentucky AG is not familiar with the regulations or the medical board opinion or, if the Kentucky AG is familiar with the regulations and the opinion, that the AG would not oppose both the tele-induction of buprenorphine and the tele-monitoring of patients who are already on buprenorphine despite the Kentucky law to the contrary.

CONCLUSION

This Essay has summarized illustrative federal and state developments relating to the tele-induction of buprenorphine for the treatment of OUD and comes to two main conclusions. First, federal and state laws and initiatives relating to the tele-induction of buprenorphine for the treatment of OUD vary widely and, in many cases, have been in constant flux since the issuance of the Second Temporary Rule. Due to this flux, prescribers may struggle to understand whether they can tele-prescribe buprenorphine for the treatment

131. *See id.*

132. *Id.*

133. *Id*. at 2 (emphasis added) (internal citations omitted).

134. *See* Letter from the National Association of Attorneys General to Merrick Garland, Att'y Gen., Dep't of Just., Xavier Becerra, Sec'y, Dep't of Health and Hum. Serv., Anne Milgram, Adm'r, Drug Enf't Admin., Miriam Delphin-Rittmon, Ass't Sec'y, Substance Abuse & Mental Health Servs. Admin. (Nov. 16, 2022), https://www.naag.org/wp-content/uploads/2022/11/NAAG-Policy_45_AG-Telehealth-Extension-Letter-1.pdf [https://perma.cc/95AP-XJDG] (listing Kentucky AG, Daniel Cameron, as a signatory).

135. *See supra* notes 115–33 and accompanying text.

of OUD under state law and, if they can, the length of time such flexibilities will last.[136]

Nonetheless, consequences of nonconformance may be severe. Prescribers can face professional discipline as well as civil and/or criminal liability when they fail to comply with changes in the law by their respective effective dates.[137] The constant changes in the law, the lack of certainty, and the potential for professional and legal consequences have led to extraordinary confusion and, even, panic among providers who have the responsibility of caring for individuals with OUD.[138]

Second, chaos in this area is particularly unfortunate given that stability would be in everyone's best interest.[139] When states change their position on the permissibility of the tele-induction of controlled substances, patients who have relied on virtual providers must scramble to find in-person providers. Some patients are unable to do so within required time frames,[140] leading to a lack of access to buprenorphine.[141] Other patients who can access an in-person provider who is *generally* willing to accept a new patient have been told that the provider was *specifically unwilling* to accept a patient who had been in a telemedicine program for OUD, leading to further delays.[142] Although some virtual providers have innovated temporary, in-person solutions, such as Bicycle Health's "Alabama Airdrop" operation,[143] these solutions are not 100 percent effective. For example, some Alabama residents who were unable to attend the six-day-long provider airdrop lost access to their buprenorphine as a result.[144] A lack of stability

136. *See, e.g.*, Hart, *supra* note 14 (explaining that a December 2023 position change by the Georgia Board to reimpose prepandemic restrictions on virtual prescribing led to "confusion and outcry from doctors," and further noting that in January 2024, the Georgia Board reversed its position yet again and that it is continuing to revisit the issue and will provide a final answer by May 1, 2024).

137. *See, e.g.*, Hart, *supra* note 13 ("The Composite Medical Board oversees doctors in Georgia, and if it finds unprofessional conduct it can put a permanent disciplinary mark on a doctor's license, or revoke their license to practice in the state altogether.").

138. *See, e.g.*, *supra* notes 136–37.

139. The author thanks Professor Jennifer Oliva at the Indiana University Bloomington Maurer School of Law for her help in drawing this conclusion.

140. *See, e.g.*, *supra* notes 4–5 (explaining, for example, that patients located in rural areas, patients who lack access to transportation, and patients who are sensitive to the stigma associated with both OUD as well as medications for the treatment of OUD face significant, if not complete, barriers to buprenorphine access).

141. *See, e.g.*, Gliadkovskaya, *supra* note 102 (reporting that when Alabama enacted legislation in 2022 prohibiting the tele-induction of buprenorphine, virtual providers notified patients of the need to find an in-person provider; however, only about one-fifth of those patients had transferred to in-person providers; further noting that the volume of patients (80 percent) without access to in-person care was "completely unacceptable"; also noting that "[m]ajor barriers to in-person care for patients include distance, expense or long wait times. Some programs were also unwilling to accept patients who had previously been in a telemedicine program for opioid use disorder.").

142. *See id.*

143. *See supra* note 100 and accompanying text (discussing this operation, which became necessary when Alabama enacted a law prohibiting the tele-induction of controlled substances during the COVID-19 pandemic).

144. *See id.*

and clarity in federal and state law can negatively impact patients and health care outcomes. Federal and state lawmakers must stop changing their position regarding the permissibility of the tele-induction of buprenorphine for the treatment of OUD and adopt laws that permanently extend COVID-19 telemedicine flexibilities. Any other approach could have tragic consequences for individuals with OUD.